

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	William C. Brunnett et al.	Examiner:	David C. Comstock
Serial No.:	10/776,835	Group Art Unit:	3733
Filed:	February 11, 2004	Docket No.:	M190.147.101 / PD266.00
Title:	HIGH SPEED SURGICAL CUTTING INSTRUMENT		

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION UNDER 37 C.F.R § 1.132**

Sir/Madam:

I, Scott Carpenter, hereby declare that:

1. I currently reside at 1030 Buddy Crout Lane, Neptune Beach FL 32266.
2. I have earned an associates in science degree in nursing from Florida Community College in Jacksonville.
3. My previous employment history includes surgical nursing, clinical product support and product management. I've been employed with Mcdtronic Xomed, Inc. ("Xomed"), in several marketing roles since February 1999. My current title is Product Manager, Powered Rhinology. In this capacity, I market and sell high powered drills and accessories to hospitals, clinics and doctors.
4. My current employment capacity provides me with an intimate knowledge of various surgical operations that utilize high speed surgical cutting instruments. In particular, I have knowledge of cochlear implant procedures and the iatrogenic risks associated with the cochleostomy portion of this procedure. I also have the opportunity to witness these procedures being performed and discuss these procedures with doctors that perform the procedures.
5. I have reviewed and understand the contents of the present application as described in U.S. Patent Application Publication No. 2005/0177168 ("the '168 Publication"). Additionally, I have reviewed and understand the claims set forth in the Amendment that is filed herewith.
6. Features described in the '168 Publication and recited in the present claims are marketed and sold by Xomed under the Visao® brand name. Attached as Exhibit A is a document titled "The Visao® High-Speed Otologic Drill Catalog". The catalog, Exhibit A, describes curved burs that operate at high speeds for cochleostomies, middle fossa acoustic

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neuromas and infralabyrinth approaches to the petrous apex. In particular, the curved burs in the catalog embody features recited in the claims of the present application. For example, claim 1 recites an instrument having a curved segment that allows rotation of an inner wire at a speed in excess of 50,000 RPM. These features are prominent in Xomed's marketing initiatives and have enjoyed commercial success.

7. Attached as Exhibit B is revenue data for sales in the United States of Visao® drills and burs. Drill revenue is denoted as "Capital" and bur revenue is denoted as "Disposable". In the second quarter of fiscal year 2004, since the introduction of curved burs, revenue for bur sales have steadily increased. For example, bur revenue in fiscal year 2004 was \$1.8 million and bur revenue in fiscal year 2008 was \$4.6 million. Thus, in a period of five years, bur revenue has more than doubled.

8. Attached as Exhibit C is a chart showing the number of drills and the number of curved burs sold by Xomed from the second quarter of fiscal year 2005 to the fourth quarter of fiscal year 2008. Sale volumes have risen steadily over the time period shown. For example, for a period from Quarter 2, 2005 to Quarter 4, 2005, the volume of curved burs were less than 200 for each quarter. In contrast, for a period from Quarter 2, 2008 to Quarter 4, 2008, the volume of curved burs were more than 1,000 for each quarter.

9. With particular reference to cochlear implant procedures, curved bur sales have established significant market share increases for a period from calendar year 2005 to calendar year 2007. Exhibit D shows a chart of cochlear implant procedures relative to Visao® curved bur sales. In particular, calendar year 2007 figures show that Visao® curved burs from Xomed were used in nearly half of cochlear implant procedures performed in the U.S.

10. Based on the above, as well as evidence presented in the Exhibits attached hereto, it is my belief that the Visao® curved bur has produced substantial commercial success in the marketplace relative to other burs. In particular, the curved bur and high operational speeds of Visao® products has provided substantial commercial success.

**Declaration under 37 C.F.R. § 1.131**

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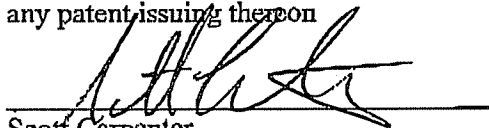
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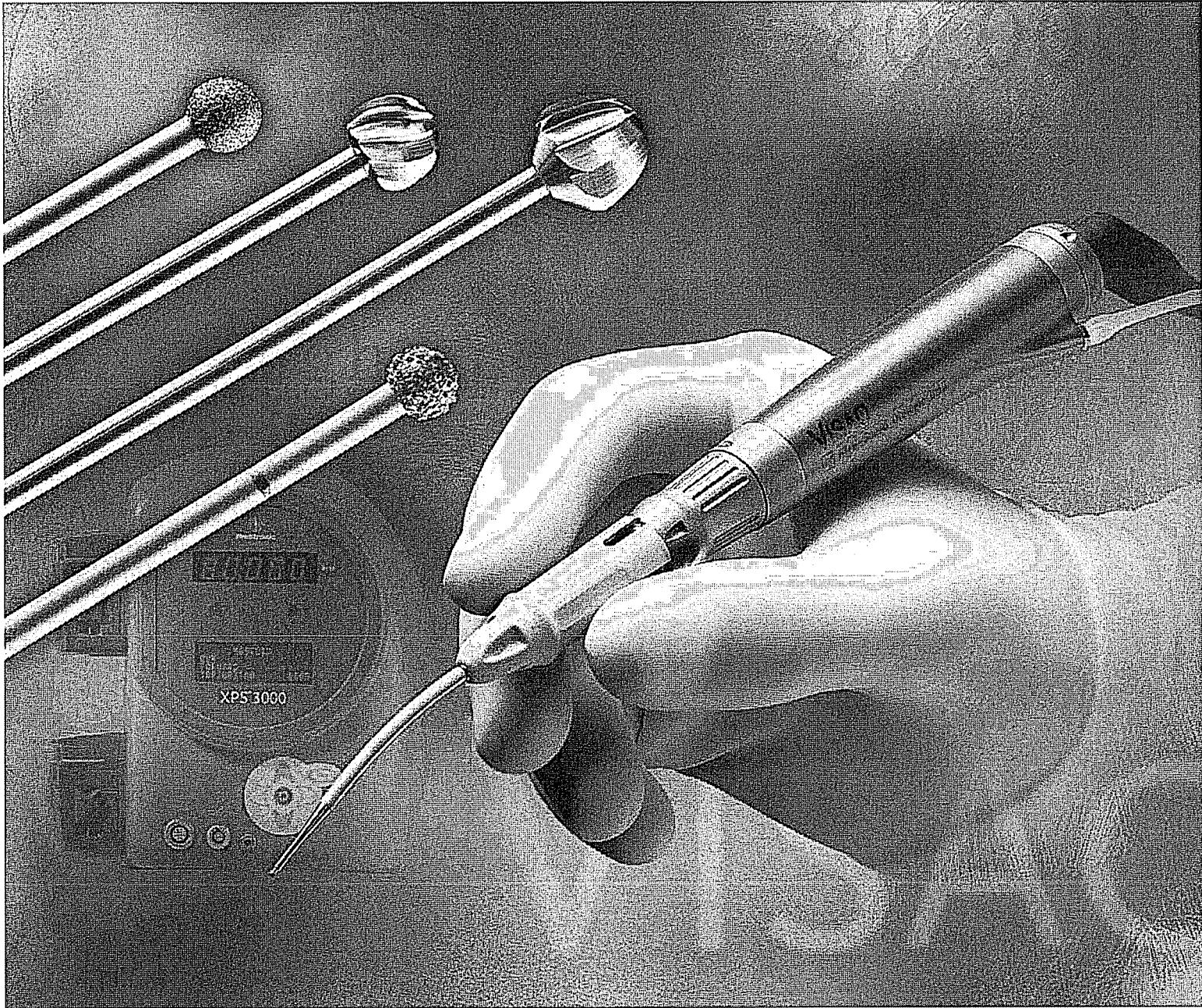
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11. I declare that all statements made herein are my own knowledge and are true and that all statements made on information are believed to be true; and further, that these statements are made with the knowledge that willful, false statements and the like so-made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of United States Code, and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon

  
\_\_\_\_\_  
Scott Carpenter

August 25<sup>th</sup>, 2008  
Date

## THE VISAO® HIGH-SPEED OTOLOGIC DRILL CATALOG



**EXHIBIT A**

# Visao® High-Speed Otologic Drill with the XPS® 3000 System

## *Revolutionary design for neurotology*

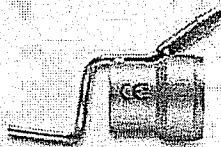
The Visao® High-Speed Otologic Drill allows remarkable surgical visibility and access with patent-pending curved burs... just what you need for cochleostomies, middle fossa acoustic neuromas and infralabyrinth approaches to the petrous apex.

The Visao drill's 80,000 rpm and high torque allow for delicate, precise removal of bone and tissue with virtually no start-up "kick."

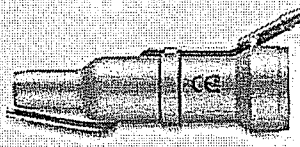
The lightweight, ergonomic titanium exterior provides a well-balanced, comfortable handpiece with low operating temperatures and integrated water-cooling.

### Exhibit A

The Visao® High-Speed Otologic Drill utilizes an adjustable irrigation collar, as well as irrigating and non-irrigating bur guards for straight burs.



33-34610 Irrigation Collar

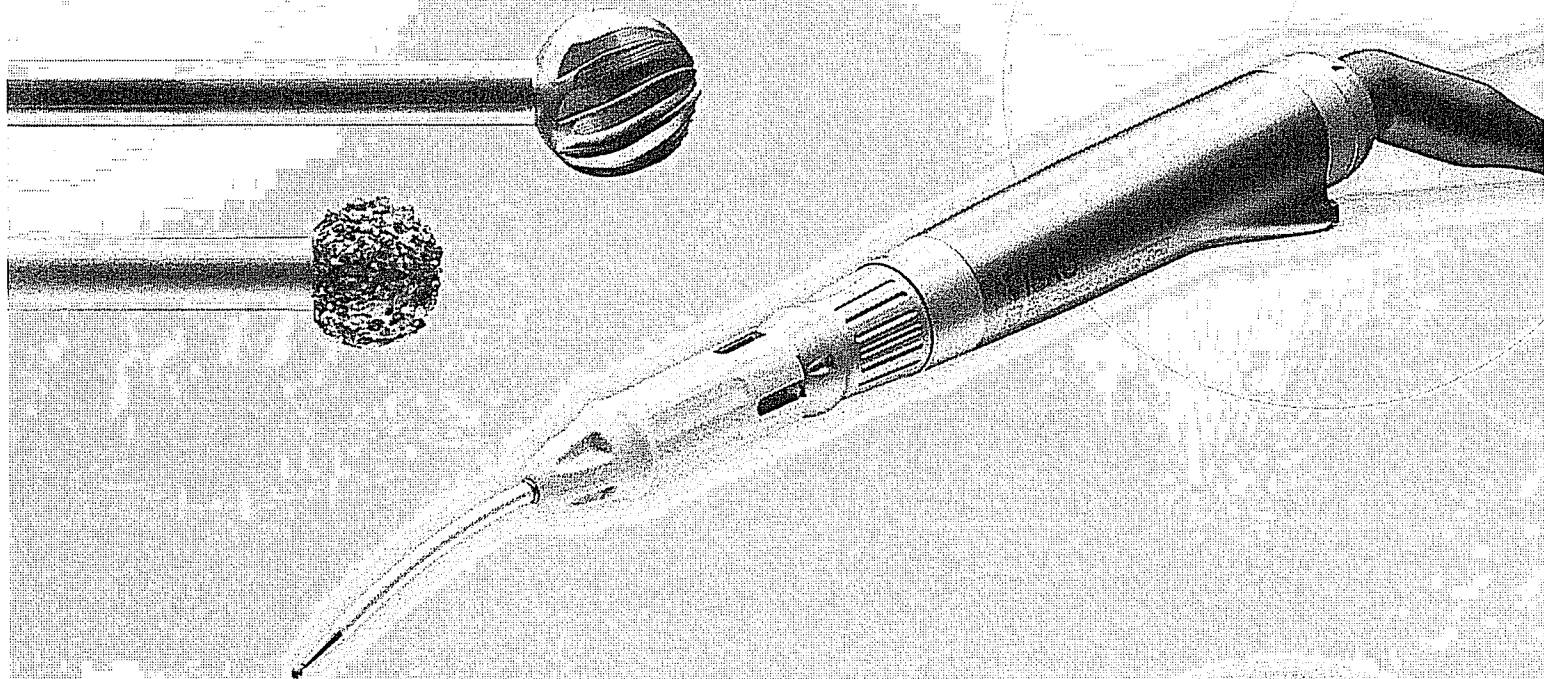


33-34635 Extended Bur Guard  
with Irrigation

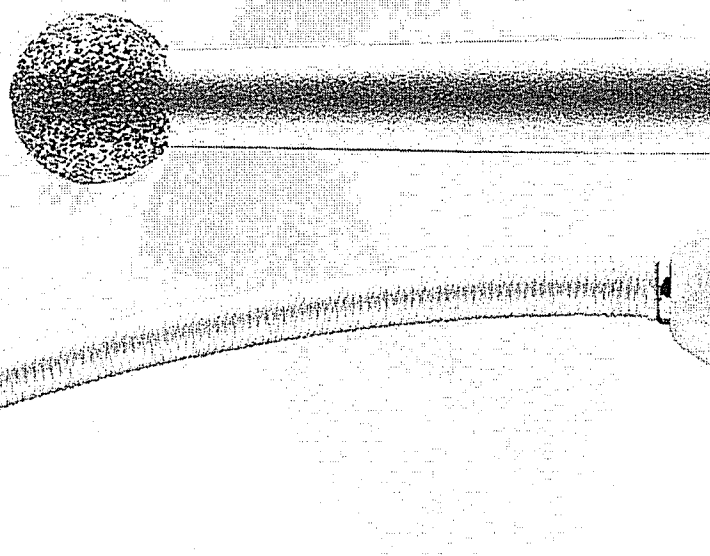
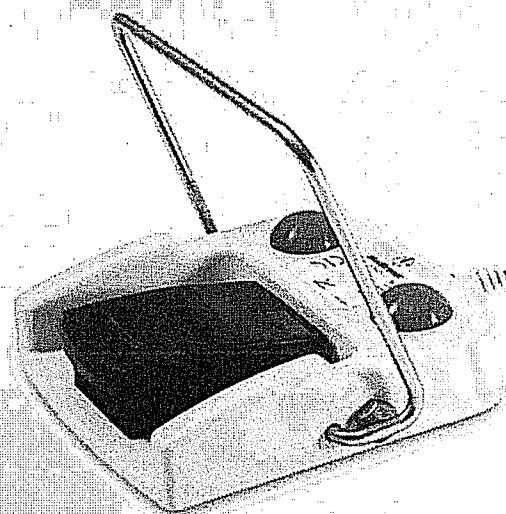


33-34625 Extended Bur Guard  
without Irrigation





- High-speed curved burs in various sizes help provide better visibility and access
- High-speed curved burs feature an outer, non-rotating tube design to help protect critical anatomy from mechanical injury
- 80,000 rpm forward and reverse operation provides power in debulking operations and finesse in delicate procedures
- Electric motor reduces industrial noise compared to traditional pneumatic handpieces



# high-speed cochleostomy burs

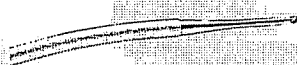
- Innovative, 20° curved design • 1 per box
- Use at speeds up to 80,000 rpm

Curved Fluted Cutting Burs	Bur Diameter (mm)	SHAFT LENGTH
		98mm



1.5

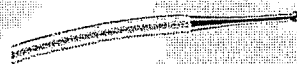
31-151598E



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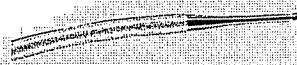
31-151098E

Curved Fine Diamond Burs	Bur Diameter (mm)	SHAFT LENGTH
		98mm



1.5

31-181598E



1

31-181098E



0.6

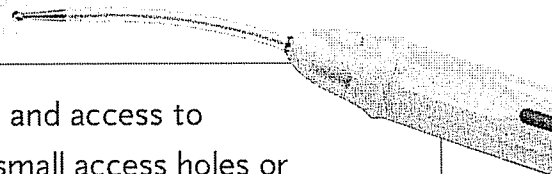
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0.5

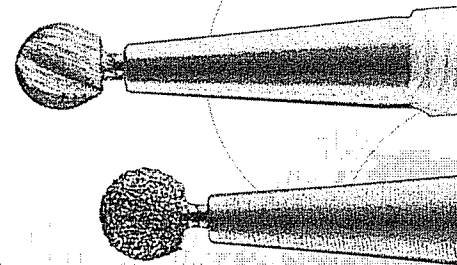
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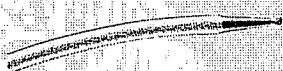
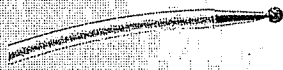

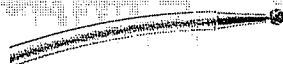
The revolutionary 20° curved burs allow better visibility and access to the surgical field during complex procedures with only small access holes or speculums. Each bur's thin outer sheath leaves very little rotating shaft exposed, which helps protect delicate tissue from a spinning shaft.



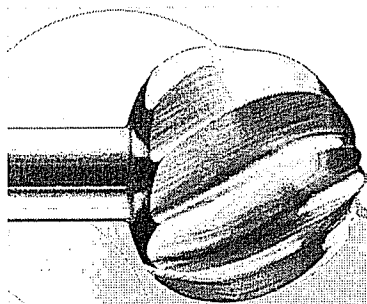
# high-speed curved burs

- Innovative, 20° curved design • 1 per box
- Use at speeds up to 80,000 rpm





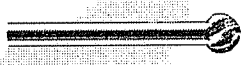
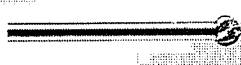


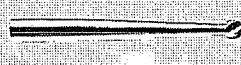
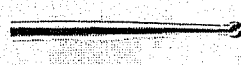
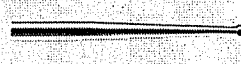
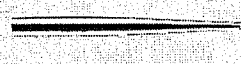
Curved Fluted Cutting Burs	Bur Diameter (mm)	S H A F T   L E N G T H	
		90mm	115mm
	2	31-152090E	31-1720115E
	1.5		31-1715115E
	1		31-1710115E
Curved Fine Diamond Burs	Bur Diameter (mm)	90mm	
		90mm	115mm
	2	31-182090E	31-1920115E
	1		31-1910115E
Curved Coarse Diamond Burs	Bur Diameter (mm)	90mm	
		90mm	115mm
	2	31-202090E	31-2120115E





# round steel burs

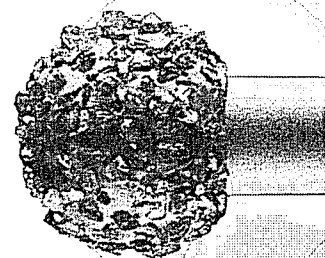
- 5 per box
- Use at speeds up to 80,000 rpm

	Bur Diameter (mm)	Bur Type	Part Number	Bur Length
	7	Standard	31-317045U	52mm
		Medium*	31-317057U	64mm
		Long*	31-317062U	69mm
	6	Standard	31-316046U	52mm
		Medium*	31-316058U	64mm
		Long*	31-316063U	69mm
	5	Standard	31-315047U	52mm
		Medium*	31-315059U	64mm
		Long*	31-315066U	71mm
	4	Standard	31-314053U	57mm
		Medium*	31-314065U	69mm
		Long*	31-314068U	72mm
	3.5	Standard	31-313553U	57mm
		Long*	31-313568U	72mm
	3	Standard	31-313054U	57mm
		Long*	31-313069U	72mm
		X-Long*	31-12974C	78mm
	2.5	Standard	31-312554	57mm
		Long*	31-312569	72mm
	2	Standard	31-312055	57mm
		Long*	31-312070	72mm
		X-Long*	31-142075	77mm
	1.5	Standard	31-311555	57mm
		Long*	31-311570	72mm
		X-Long*	31-141575	77mm
	1	Standard	31-311056	57mm
		Long*	31-311071	72mm
		X-Long*	31-141075	76mm



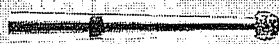






\*Requires bur guard

# round coarse diamond burs

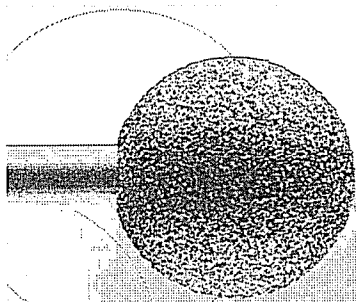
## round coarse diamond burs



- 1 per box
- Use at speeds up to 80,000 rpm





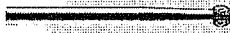



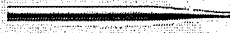

	Bur Diameter (mm)	Bur Type	Part Number	Bur Length
	6	Standard	31-116050	56mm
		Medium	31-116058	64mm
		Long*	31-116065	71mm
	5	Standard	31-115051	56mm
		Medium	31-115059	64mm
		Long*	31-115066	71mm
	4	Standard	31-114053	57mm
		Medium	31-114065	69mm
		X-Long*	31-114075	79mm
	3.5	Standard	31-113554	57mm
		Long*	31-113568	72mm
	3	Standard	31-113054	57mm
		Long*	31-113069	72mm
		X-Long*	31-113075	78mm
	2.5	Standard	31-112554	57mm
		Long*	31-112569	72mm
		X-Long*	31-112575	78mm
	2	Standard	31-112055	57mm
		Long*	31-112070	72mm
		X-Long*	31-112075	77mm
	1.5	Standard	31-111555	57mm
		Long*	31-111570	72mm
		X-Long*	31-111575	77mm
	1	Standard	31-111056	57mm
		Long*	31-111071	72mm
		X-Long*	31-111075	76mm

\*Requires bur guard



# round fine diamond burs

- 1 per box
- Use at speeds up to 80,000 rpm

	Bur Diameter (mm)	Bur Type	Part Number	Bur Length
	6	Standard	31-136050	56mm
		Medium	31-136058	64mm
		Long*	31-136065	71mm
	5	Standard	31-135051	56mm
		Medium	31-135059	64mm
		Long*	31-135066	71mm
	4	Standard	31-134053	57mm
		Medium	31-134065	69mm
		Long*	31-134068	72mm
	3.5	Standard	31-133553	57mm
		Long*	31-133568	72mm
	3	Standard	31-133054	57mm
		Long*	31-133069	72mm
		X-Long*	31-103075	78mm
	2.5	Standard	31-132554	57mm
		Long*	31-132569	72mm
		X-Long*	31-102575	78mm
	2	Standard	31-132055	57mm
		Long*	31-132070	72mm
		X-Long*	31-102075	77mm
	1.5	Standard	31-131555	57mm
		Long*	31-131570	72mm
		X-Long*	31-101575	77mm
	1	Standard	31-131056	57mm
		Long*	31-131071	72mm
		X-Long*	31-101075	76mm
	0.5	Standard	31-130556	57mm
		Long*	31-130571	72mm
		X-Long*	31-100575	76mm

\*Requires bur guard





# ordering information

- 33-33616 Visao® High-Speed Otologic Drill - System 16**  
**33-18503** Xcalibur® Irrigation Tubing Set, Sterile, 4/box  
**33-18506** Xcalibur High-Speed Drill Coolant Tubing Set, 2/box  
**33-34800** Visao High-Speed Otologic Drill  
**33-34625** Visao High-Speed Otologic Drill Extended Bur Guard without Irrigation  
**33-34635** Visao High-Speed Otologic Drill Extended Bur Guard with Irrigation  
**33-34610** Visao High-Speed Otologic Drill Irrigation Sleeve Assembly  
**33-34895** Visao High-Speed Otologic Drill Sterilization Tray
- 33-33617 Visao High-Speed Otologic Drill, IGS Trackable - System 17**  
**33-18503** Xcalibur Irrigation Tubing Set, Sterile, 4/box  
**33-18506** Xcalibur High-Speed Drill Coolant Tubing Set, 2/box  
**33-34800T** Visao High-Speed Otologic Drill, IGS Trackable  
**33-34625** Visao High-Speed Otologic Drill Extended Bur Guard without Irrigation  
**33-34635** Visao High-Speed Otologic Drill Extended Bur Guard with Irrigation  
**33-34610** Visao High-Speed Otologic Drill Irrigation Sleeve Assembly  
**33-34895** Visao High-Speed Otologic Drill Sterilization Tray
- 33-33618 Visao High-Speed Otologic Drill and XPS 3000 Console - System 18**  
**33-18503** Xcalibur Irrigation Tubing Set, Sterile, 4/box  
**33-18506** Xcalibur High-Speed Drill Coolant Tubing Set, 2/box  
**33-34800** Visao High-Speed Otologic Drill  
**33-34625** Visao High-Speed Otologic Drill Extended Bur Guard without Irrigation  
**33-34635** Visao High-Speed Otologic Drill Extended Bur Guard with Irrigation  
**33-34610** Visao High-Speed Otologic Drill Irrigation Sleeve Assembly  
**33-34895** Visao High-Speed Otologic Drill Sterilization Tray  
**18-97102** XPS® 3000 Console, Two Pumps  
**18-97821** Power Cord, 6 meters  
**18-95420** Multi-Function Footswitch, Single Pedal  
**18-97510** XPS IV Pole Basket for Footswitch
- 18-97019 XPS 3000 Straightshot® M4 Microdebrider, Visao High-Speed Drill and XPS 3000 Console - System 19**  
**18-97102** XPS 3000 Console, Two Pumps  
**18-98200T** XPS Straightshot M4 High-Speed IGS-Trackable Microdebrider  
**18-97821** Power Cord, 6 meters  
**18-95420** Multi-Function Footswitch, Single Pedal  
**18-97510** XPS IV Pole Basket for Footswitch  
**18-98400** XPS Straightshot M4 Sterilization Tray  
**33-18503** Xcalibur Irrigation Tubing Set, Sterile, 4/box  
**33-18506** Xcalibur High-Speed Drill Coolant Tubing Set, 2/box  
**33-34800** Visao High-Speed Otologic Drill  
**33-34625** Visao High-Speed Otologic Drill Extended Bur Guard without Irrigation  
**33-34635** Visao High-Speed Otologic Drill Extended Bur Guard with Irrigation  
**33-34610** Visao High-Speed Otologic Drill Irrigation Sleeve Assembly  
**33-34895** Visao High-Speed Otologic Drill Sterilization Tray



# ordering information

## **18-97020 XPS 3000 Straightshot M4 Microdebrider, Visao High-Speed Drill, Skeeter® and XPS 3000 Console - System 20**

- 18-97102 XPS 3000 Console, Two Pumps
- 18-98200T XPS Straightshot M4 High-Speed IGS-Trackable Microdebrider
- 18-97821 Power Cord, 6 meters
- 18-95420 Multi-Function Footswitch, Single Pedal
- 18-97510 XPS IV Pole Basket for Footswitch
- 18-98400 XPS Straightshot M4 Sterilization Tray
- 33-18503 Xcalibur Irrigation Tubing Set, Sterile, 4/box
- 33-18506 Xcalibur High-Speed Drill Coolant Tubing Set, 2/box
- 33-34800 Visao High-Speed Otologic Drill
- 33-34625 Visao High-Speed Otologic Drill Extended Bur Guard without Irrigation
- 33-34635 Visao High-Speed Otologic Drill Extended Bur Guard with Irrigation
- 33-34610 Visao High-Speed Otologic Drill Irrigation Sleeve Assembly
- 33-34895 Visao High-Speed Otologic Drill Sterilization Tray
- 30-55601 Skeeter® Ultralite Handpiece
- 31-55615 Skeeter Sterilization Tray

## **18-97021 XPS 3000 Visao High-Speed Drill, Skeeter and XPS 3000 Console - System 21**

- 18-97102 XPS 3000 Console, Two Pumps
- 18-97821 Power Cord, 6 meters
- 18-95420 Multi-Function Footswitch, Single Pedal
- 18-97510 XPS IV Pole Basket for Footswitch
- 33-18503 Xcalibur Irrigation Tubing Set, Sterile, 4/box
- 33-18506 Xcalibur High-Speed Drill Coolant Tubing Set, 2/box
- 33-34800 Visao High-Speed Otologic Drill
- 33-34625 Visao High-Speed Otologic Drill Extended Bur Guard without Irrigation
- 33-34635 Visao High-Speed Otologic Drill Extended Bur Guard with Irrigation
- 33-34610 Visao High-Speed Otologic Drill Irrigation Sleeve Assembly
- 33-34895 Visao High-Speed Otologic Drill Sterilization Tray
- 30-55601 Skeeter Ultralite Handpiece
- 31-55615 Skeeter Sterilization Tray

*For further information, please call Medtronic ENT at 800.874.5797 or 904-296-9600.*

*You may also consult our website at [www.MedtronicENT.com](http://www.MedtronicENT.com).*



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**International Telephone Numbers**

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Belgium: 32-2456-09-09	Lebanon: 961-1-370-670
Canada: 1-800-217-1617	Luxembourg: 32-2456-09-09
China: 86-21-50800998	Netherlands: 31-45-566-8371
France: 33-470-679-800	Poland: 48-22-465-6942
Germany: 49-211-5293-209	Singapore: 65-6776-6255
Hong Kong: 852-2919-1312	Spain: 34-91-625-05-40
India: 91-22-26836733	UK: 44-1923-205-166
Italy: 39-02-24137-324	USA: 1-904-296-9600
Japan: 81-6-4795-1506	

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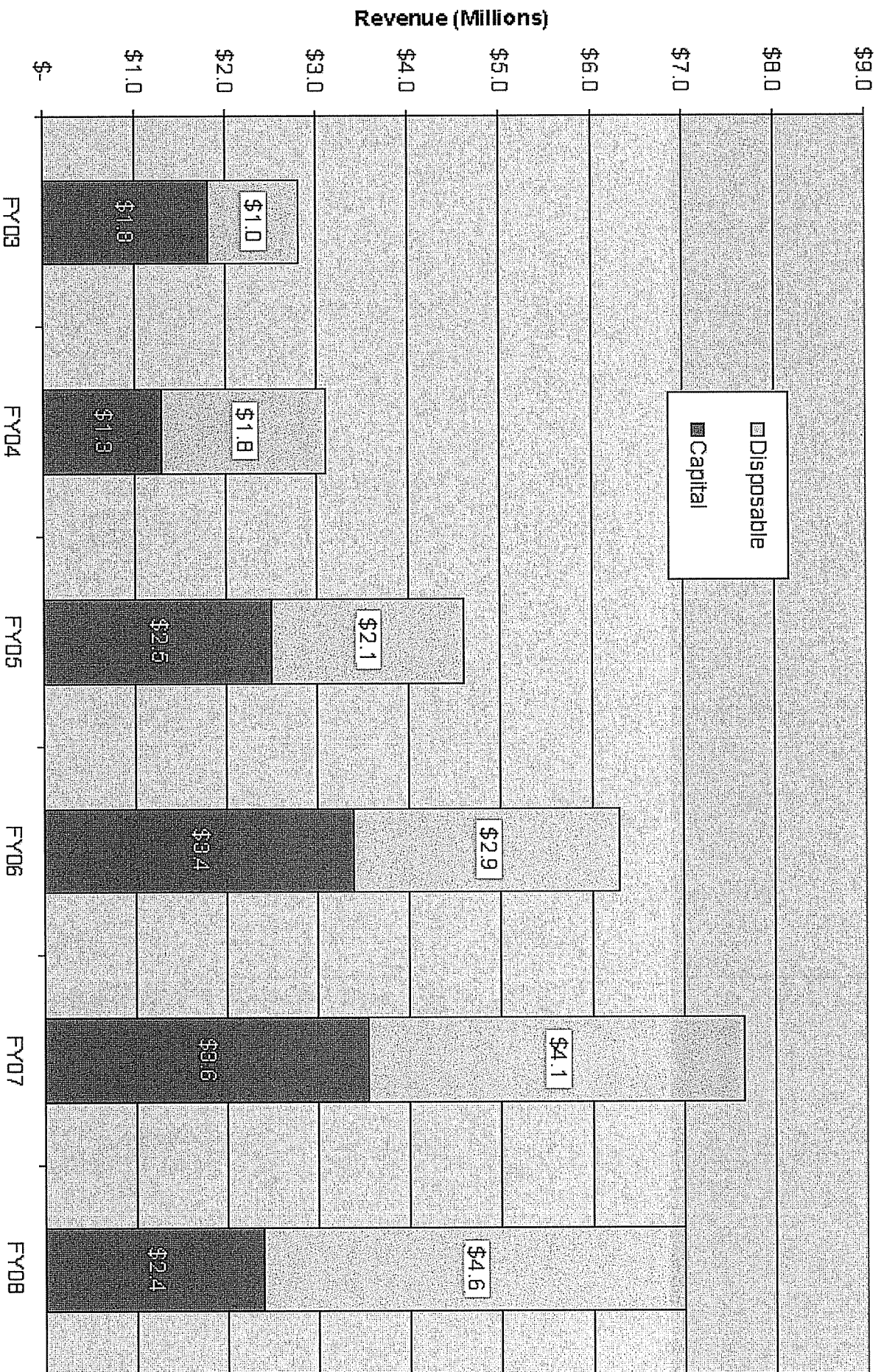
HEART AND VASCULAR DISEASE • NEUROLOGICAL DISORDERS • PAIN • SPINAL DISORDERS • DIABETES  
UROLOGIC DISORDERS • DIGESTIVE SYSTEM DISORDERS • EYE, EAR, NOSE AND THROAT DISORDERS



**Medtronic**

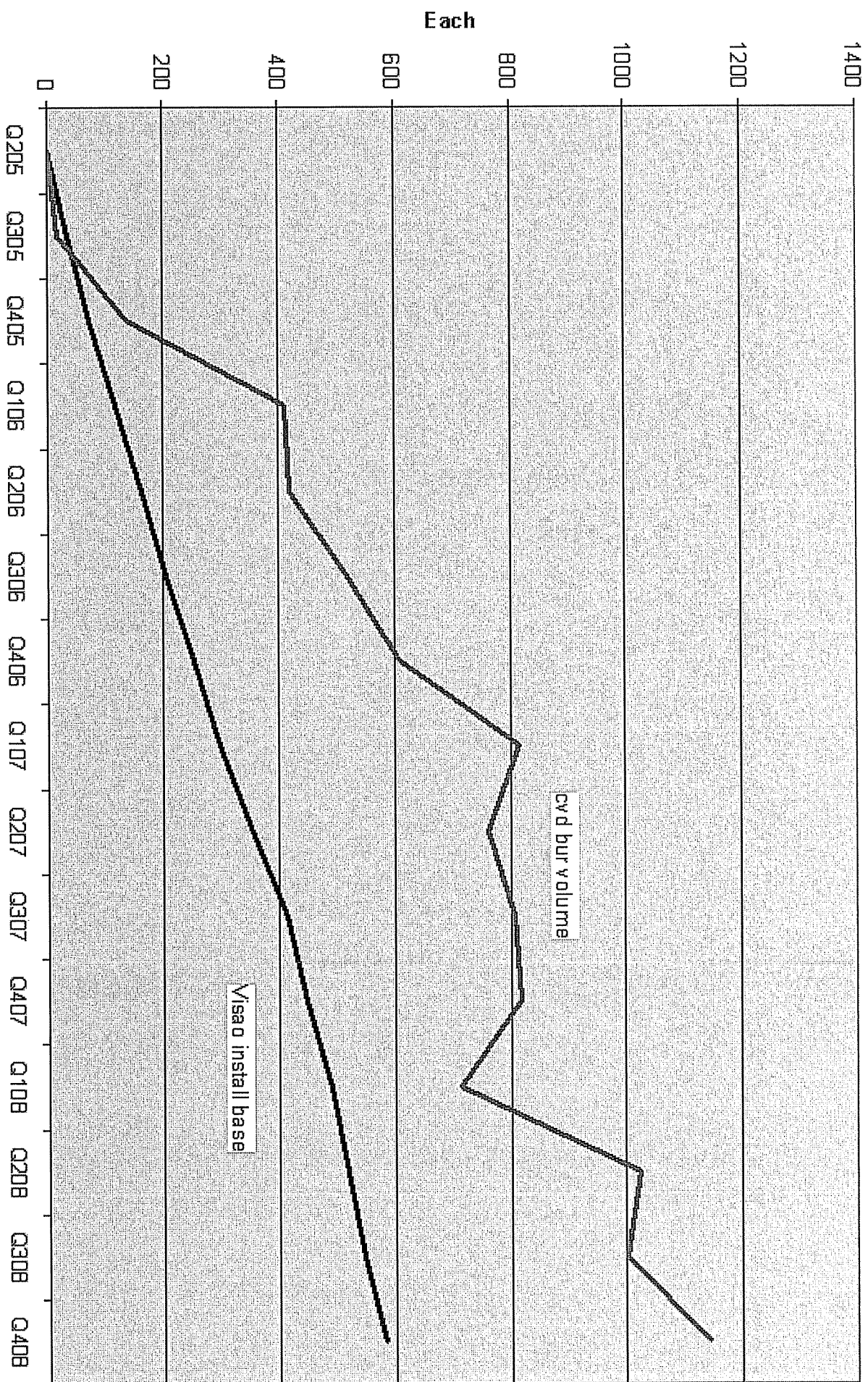
*Alleviating Pain • Restoring Health • Extending Life*

# Domestic Drill Business

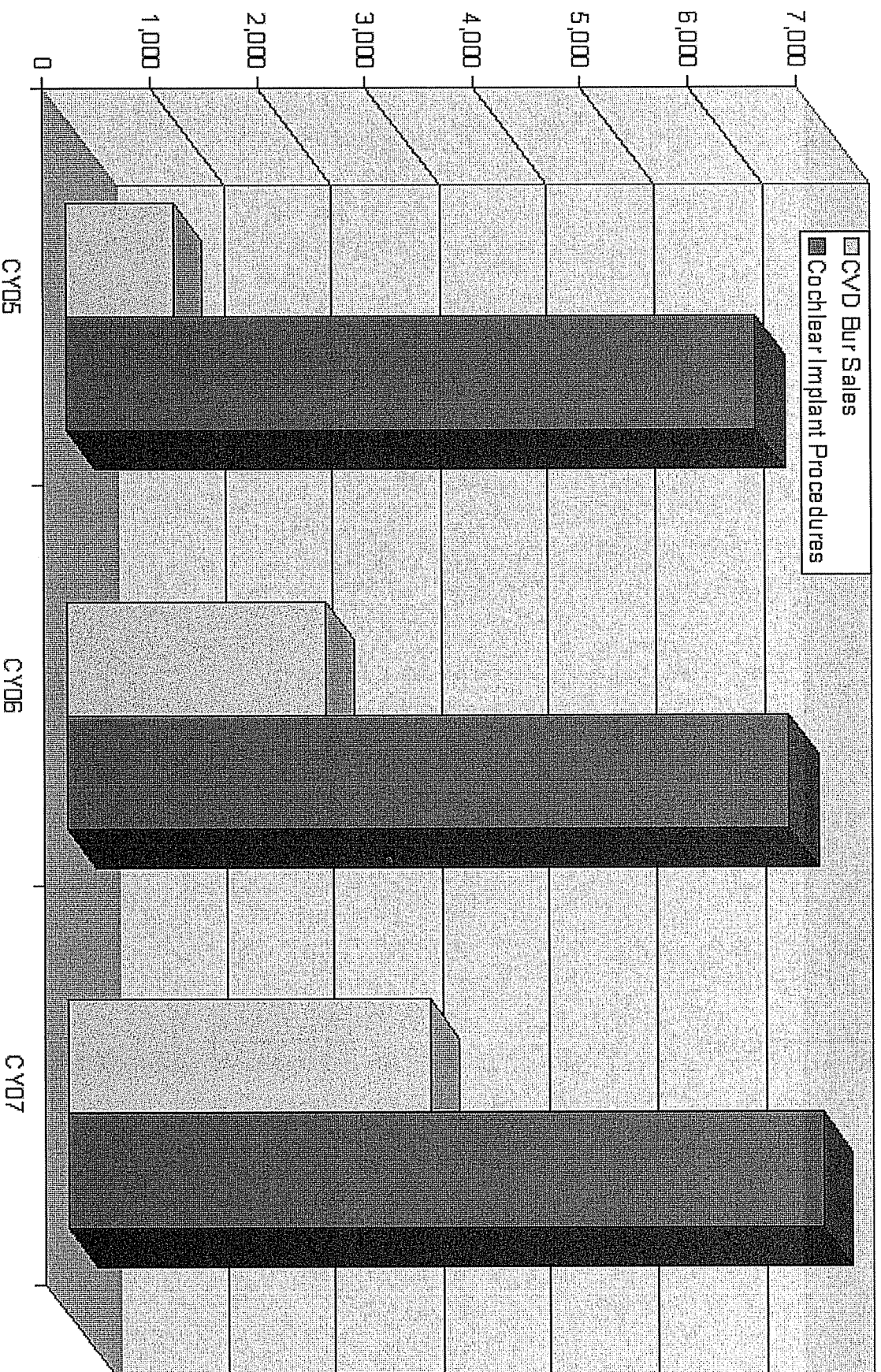




## Quarterly installed base &amp; curved bur volume



# Cochlear Implant Procedures & Relative Medtronic ENT Curved Bur Sales (USA Only)



**EXHIBIT D**